UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,029	07/26/2000	PETER HIMMELSBACH	BEIERSDORF-6	5165

7055 7590 08/02/2006

GREENBLUM & BERNSTEIN, P.L.C.
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER	
PIZIALI, ANDREW T	

ART UNIT	PAPER NUMBER
1771	

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/601,029	HIMMELSBACH ET AL.	
	Examiner	Art Unit	
	Andrew T. Piziali	1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/6/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 4/27/2006 has been entered. Applicant's amendment necessitated the new grounds of rejection presented in this Office action.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 7/6/2006 was considered by the examiner. USPN 6,074,965 is crossed out because the reference was already cited by the examiner in the Notice of References Cited mailed on 7/23/2002.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 37-43, 45-52 and 55-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle et al. (hereinafter referred to as Merkle) in view of USPN 6,479,073 to Lucast et al. (hereinafter referred to as Lucast '073) in view of USPN 5,547,223 to Koketsu et al. (hereinafter referred to as Koketsu).

Regarding claims 37-43, 45-52 and 55-65, Merkle discloses a backing material for

medical purposes, and an adhesive composition on one side of the backing material, the adhesive composition being a hot melt composition comprising a styrene block copolymer, the adhesive composition further comprising at least one pharmacologically active substance (see entire document including the abstract, column 3, lines 4-10, and the paragraph bridging columns 4 and 5).

Merkle discloses that the backing layer may be a polyester film (see Examples), but Merkle is silent with regards to specific polyester film structures. Therefore, it would have been necessary and thus obvious to look to the prior art for conventional backing layer structures. Lucast '073 provides this conventional teaching showing that it is known in the art to use a nonwoven backing layer overstitched by yarns (see entire document including the paragraph bridging columns 2 and 3). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the backing layer from a nonwoven overstitched by yarns, as taught by Lucast '076, motivated by the expectation of successfully practicing the invention of Merkle and because it is within the general skill of a worker in the art to select a known backing layer structure on the basis of its suitability and desired characteristics.

Lucast '076 does not appear to mention how many stitches (per cm) are present on the backing layer, but Koketsu discloses that it is known in the art that the number of stitches is a result effective variable that would alter the strength of the web, with more stitches supplying a stronger web (see entire document including column 7, lines 16-32). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide 5 to 50 longitudinal stitches per cm in order to create a stitch-bonded fabric with a desired strength and

rigidity and because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claims 39-43, 58-59 and 65, considering that the backing material taught by the applied prior art is substantially identical to the claimed backing material (stitch-bonded polyester nonwoven with 5 to 50 stitches per cm), it appears that the backing material inherently possesses the claimed properties.

The Patent and Trademark Office can require applicants to prove that prior art products do not necessarily or inherently possess characteristics of claimed products where claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes; burden of proof is on applicants where rejection based on inherency under 35 U.S.C. § 102 or on prima facie obviousness under 35 U.S.C. § 103, jointly or alternatively, and Patent and Trademark Office's inability to manufacture products or to obtain and compare prior art products evidences fairness of this rejection, *In re Best, Bolton, and Shaw*, 195 USPQ 431 (CCPA 1977).

Regarding claims 45 and 46, Merkel discloses that 100% of one side of the backing layer may be coated with the adhesive composition while the other side of the backing layer may be uncoated with the adhesive (see Examples).

Regarding claims 47 and 48, Merkel does not appear to mention the weight per unit area of the adhesive on the backing material, but the amount of adhesive is a result effective variable that would affect the degree of adhesion the tape would have to the skin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide between 90 to 500 grams per square meter of adhesive in order to create a medical tape with the

optimum amount of adhesion strength fit for its intended use on human skin and because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claims 49-52, Merkel discloses that the block copolymer may be a triple-block copolymer wherein the block A comprises polystyrene and the block B comprises one or more monomer units such as ethylene and butylenes (abstract).

Regarding claims 51 and 52, Merkel discloses that the total concentration of styrene in the block copolymer may be 10 to 50 weight percent (column 4, lines 40-42).

Regarding claims 55 and 61, Merkel discloses that adhesive composition may comprise from 10 to 80% block copolymers (column 4, lines 21-43).

Regarding claims 56 and 57, Merkel discloses that the adhesive composition may have a softening point of from 80 to 140C (column 4, lines 55-64).

Regarding claims 60 and 61, Merkel discloses that the pharmacologically active substance may be present in therapeutically active amounts (column 3, lines 4-10). The examiner takes Official Notice that 0.01 to 20% by weight includes therapeutically active amounts.

Regarding claim 62, Merkel does not appear to mention the addition of foaming agents, but Lucast '073 discloses that it is known in the art to add foaming agents to an adhesive (column 5, lines 16-23). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a foaming agent to the adhesive, as disclosed by Lucast '076, because some adhesive applications desire foamed adhesive.

Regarding claim 63, Merkel discloses that the adhesive composition may be on one side of the backing material and a release layer may be on the opposite side (see Examples).

Regarding claim 64, Merkel discloses that the backing material may further comprise a polyester film (considered to read on the claimed wound pad) on the adhesive composition (see Examples).

5. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu as applied to claims 37-43, 45-52 and 55-65 above, and further in view of USPN 6,074,965 to Bodenschatz et al. (hereinafter referred to as Bodenschatz).

Merkel does not appear to mention reinforcing fibers in the backing layer, but Bodenschatz discloses that it is known in the art to use reinforcing fibers having a strength of over 60 cN/tex in a backing layer (see entire document including abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add reinforcing fibers to the backing layer, as taught by Bodenschatz, because the reinforcing fibers would advantageously increase strength.

6. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu as applied to claims 37-43, 45-52 and 55-65 above, and further in view of USPN 4,722,857 to Tomioka et al. (hereinafter referred to as Tomioka).

Merkel does not appear to mention reinforcing fibers in the backing layer, but Tomioka discloses that it is known in the bandage art to use reinforcing fibers in a nonwoven material (see entire document including column 1, lines 6-10, column 3, lines 41-58, and column 8, lines 20-

24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add reinforcing fibers to the nonwoven backing layer, as taught by Tomioka, because the reinforcing fibers would advantageously increase strength. It is noted that Tomioka discloses the use of materials (such as polyester and nylon) substantially identical to the high-strength materials disclosed in the current specification (see page 14, lines 6-11), therefore, it appears the fibers would inherently possess the claimed strength.

7. Claims 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu as applied to claims 37-43, 45-52 and 55-65 above, and further in view of USPN 5,863,977 to Fischer et al. (hereinafter referred to as Fischer).

Regarding claims 53 and 54, Merkle does not appear to mention the addition of a diblock copolymer, but Fischer discloses that it is known in the art to add a diblock copolymer to a triblock copolymer adhesive to improve tack properties and/or improve processability (see entire document including the paragraph bridging columns 2 and 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a diblock copolymer to the triblock copolymer adhesive, as taught by Fischer, to improve tack properties and/or improve processability.

Regarding claim 54, Merkel discloses that the triblock copolymer may be present in an amount of 10 to 80% and a tackifier may be present in an amount of 20 to 90% (column 4, lines 21-52), therefore, the art teaches that the diblock is to be present in an amount of less than 80% by weight.

8. Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu as applied to claims 37-43, 45-52 and 55-65 above, and further in view of USPN 5,489,624 to Kantner et al. (hereinafter referred to as Kantner).

Merkle does not appear to mention incorporating pharmacologically active agents not in co-mixture with the adhesive, but Kantner discloses that adhesive materials in the medical field can frequently be used to transport drugs through the skin (see entire document including abstract). Kantner discloses several examples of biologically active material that would exist in particle form that can be incorporated into the adhesive (see entire document including column 9, lines 28-41 and column 12, lines 14-19). It would have been obvious to a person having ordinary skill in the art at the time of the invention to incorporate active agents not in co-mixture with the adhesive composition in the medical tape, as disclosed by Kantner, in order to provide various healing properties to the tape.

9. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu as applied to claims 37-43, 45-52 and 55-65 above, and further in view of USPN 5,407,717 to Lucast et al. (hereinafter referred to as Lucast '717).

Merkel does not appear to mention sterilizing the adhesive composition, but Lucast '717 discloses that adhesive tapes that are used on human skin must be sterilized (see entire document including column 11, lines 5-10). It would have been obvious to a person having ordinary skill in the art at the time of the invention to sterilize the adhesive composition, as taught by Lucast '717, in order to make it safe for use on human skin.

10. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu as applied to claims 37-43, 45-52 and 55-65 above, and further in view of USPN 5,059,189 to Cilento et al. (hereinafter referred to as Cilento).

Merkle appears to be is silent with regards to specific pharmacologically active substances, therefore, it would have been necessary and thus obvious to look to the prior art for conventional pharmacologically active substances. Cilento provides this conventional teaching showing that it is known in the art to use pharmacologically active substances such as camphor, lidocaine, or the like (see entire document including column 6, lines 24-41). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the pharmacologically active substance from camphor or lidocaine, as disclosed by Cilento, motivated by the expectation of successfully practicing the invention of Merkle.

11. Claims 69-73, 75-82 and 85-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu in view of USPN 3,967,472 to Wildeman et al. (hereinafter referred to as Wildeman).

Regarding claims 69-73, 75-82 and 85-95, Merkle discloses a backing material for medical purposes, and an adhesive composition on one side of the backing material, the adhesive composition being a hot melt composition comprising a styrene block copolymer, the adhesive composition further comprising at least one pharmacologically active substance (see entire document including the abstract, column 3, lines 4-10, and the paragraph bridging columns 4 and 5).

Merkle discloses that the backing layer may be a polyester film (see Examples), but Merkle is silent with regards to specific polyester film structures. Therefore, it would have been necessary and thus obvious to look to the prior art for conventional backing layer structures. Lucast '073 provides this conventional teaching showing that it is known in the art to use a nonwoven backing layer overstitched by yarns (see entire document including the paragraph bridging columns 2 and 3). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the backing layer from a nonwoven overstitched by yarns, as taught by Lucast '076, motivated by the expectation of successfully practicing the invention of Merkle and because it is within the general skill of a worker in the art to select a known backing layer structure on the basis of its suitability and desired characteristics.

Lucast '076 does not appear to mention how many stitches (per cm) are present on the backing layer, but Koketsu discloses that it is known in the art that the number of stitches is a result effective variable that would alter the strength of the web, with more stitches supplying a stronger web (see entire document including column 7, lines 16-32). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide 5 to 50 longitudinal stitches per cm in order to create a stitch-bonded fabric with a desired strength and rigidity and because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Lucast '076 does not appear to mention the stitches of the fabric being formed from loops from the fibers of the web, but Wildeman discloses that it is known in the art that stitch-bonded fabrics may be stitched with the loops from the web (see entire document including column 3, lines 40-68). It would have been obvious to a person having ordinary skill in the art at the time

of the invention to stitch the fabric of Lucast '076 with loops from the web, as disclosed by Wildeman, in order to avoid using extra stitching thread.

Regarding claims 71-73, 88-89 and 95, considering that the backing material taught by the applied prior art is substantially identical to the claimed backing material (stitch-bonded polyester nonwoven with 5 to 50 stitches per cm), it appears that the backing material inherently possesses the claimed properties.

Regarding claim 72, Merkel does not appear to mention the use of a polyamide (such as nylon) for the backing material, but Lucast '073 discloses that it is known in the art to use nylon backing material (column 3, lines 19-36). Considering that the specification teaches that a backing material of this kind generates the claimed property (see page 10, lines 1-8), it appears that the backing material inherently possesses the claimed property.

Regarding claims 75 and 76, Merkel discloses that 100% of one side of the backing layer may be coated with the adhesive composition while the other side of the backing layer may be uncoated with the adhesive (see Examples).

Regarding claims 77 and 78, Merkel does not appear to mention the weight per unit area of the adhesive on the backing material, but the amount of adhesive is a result effective variable that would affect the degree of adhesion the tape would have to the skin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide between 90 to 500 grams per square meter of adhesive in order to create a medical tape with the optimum amount of adhesion strength fit for its intended use on human skin and because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claims 79-82, Merkel discloses that the block copolymer may be a triple-block copolymer wherein the block A comprises polystyrene and the block B comprises one or more monomer units such as ethylene and butylenes (abstract).

Regarding claims 81 and 82, Merkel discloses that the total concentration of styrene in the block copolymer may be 10 to 50 weight percent (column 4, lines 40-42).

Regarding claims 85 and 91, Merkel discloses that adhesive composition may comprise from 10 to 80% block copolymers (column 4, lines 21-43).

Regarding claims 86 and 87, Merkel discloses that the adhesive composition may have a softening point of from 80 to 140C (column 4, lines 55-64).

Regarding claims 90 and 91, Merkel discloses that the pharmacologically active substance may be present in therapeutically active amounts (column 3, lines 4-10). The examiner takes Official Notice that 0.01 to 20% by weight includes therapeutically active amounts.

Regarding claim 92, Merkel does not appear to mention the addition of foaming agents, but Lucast '073 discloses that it is known in the art to add foaming agents to an adhesive (column 5, lines 16-23). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a foaming agent to the adhesive, as disclosed by Lucast '076, because some adhesive applications desire foamed adhesive.

Regarding claim 93, Merkel discloses that the adhesive composition may be on one side of the backing material and a release layer may be on the opposite side (see Examples).

Regarding claim 94, Merkel discloses that the backing material may further comprise a polyester film (considered to read on the claimed wound pad) on the adhesive composition (see Examples).

12. Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu in view of USPN 3,967,472 to Wildeman as applied to claims 69-73, 75-82 and 85-95 above, and further in view of USPN 6,074,965 to Bodenschatz.

Merkel does not appear to mention reinforcing fibers in the backing layer, but Bodenschatz discloses that it is known in the art to use reinforcing fibers having a strength of over 60 cN/tex in a backing layer (see entire document including abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add reinforcing fibers to the backing layer, as taught by Bodenschatz, because the reinforcing fibers would advantageously increase strength.

13. Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu in view of USPN 3,967,472 to Wildeman as applied to claims 69-73, 75-82 and 85-95 above, and further in view of USPN 4,722,857 to Tomioka.

Merkel does not appear to mention reinforcing fibers in the backing layer, but Tomioka discloses that it is known in the bandage art to use reinforcing fibers in a nonwoven material (see entire document including column 1, lines 6-10, column 3, lines 41-58, and column 8, lines 20-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add reinforcing fibers to the nonwoven backing layer, as taught by Tomioka,

because the reinforcing fibers would advantageously increase strength. It is noted that Tomioka discloses the use of materials (such as polyester and nylon) substantially identical to the high-strength materials disclosed in the current specification (see page 14, lines 6-11), therefore, it appears the fibers would inherently possess the claimed strength.

14. Claims 83 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu in view of USPN 3,967,472 to Wildeman as applied to claims 69-73, 75-82 and 85-95 above, and further in view of USPN 5,863,977 to Fischer.

Regarding claims 83 and 84, Merkle does not appear to mention the addition of a diblock copolymer, but Fischer discloses that it is known in the art to add a diblock copolymer to a triblock copolymer adhesive to improve tack properties and/or improve processability (see entire document including the paragraph bridging columns 2 and 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a diblock copolymer to the triblock copolymer adhesive, as taught by Fischer, to improve tack properties and/or improve processability.

Regarding claim 84, Merkel discloses that the triblock copolymer may be present in an amount of 10 to 80% and a tackifier may be present in an amount of 20 to 90% (column 4, lines 21-52), therefore, the art teaches that the diblock is to be present in an amount of less than 80% by weight.

15. Claim 96 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu in view of USPN 3,967,472 to Wildeman as applied to claims 69-73, 75-82 and 85-95 above, and further in view of USPN 5,489,624 to Kantner.

Merkle does not appear to mention incorporating pharmacologically active agents not in co-mixture with the adhesive, but Kantner discloses that adhesive materials in the medical field can frequently be used to transport drugs through the skin (see entire document including abstract). Kantner discloses several examples of biologically active material that would exist in particle form that can be incorporated into the adhesive (see entire document including column 9, lines 28-41 and column 12, lines 14-19). It would have been obvious to a person having ordinary skill in the art at the time of the invention to incorporate active agents not in co-mixture with the adhesive composition in the medical tape, as disclosed by Kantner, in order to provide various healing properties to the tape.

16. Claim 97 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu in view of USPN 3,967,472 to Wildeman as applied to claims 69-73, 75-82 and 85-95 above, and further in view of USPN 5,407,717 to Lucast.

Merkel does not appear to mention sterilizing the adhesive composition, but Lucast '717 discloses that adhesive tapes that are used on human skin must be sterilized (see entire document including column 11, lines 5-10). It would have been obvious to a person having ordinary skill in the art at the time of the invention to sterilize the adhesive composition, as taught by Lucast '717, in order to make it safe for use on human skin.

17. Claim 98 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu in view of USPN 3,967,472 to Wildeman as applied to claims 69-73, 75-82 and 85-95 above, and further in view of USPN 5,059,189 to Cilento.

Merkle appears to be is silent with regards to specific pharmacologically active substances, therefore, it would have been necessary and thus obvious to look to the prior art for conventional pharmacologically active substances. Cilento provides this conventional teaching showing that it is known in the art to use pharmacologically active substances such as camphor, lidocaine, or the like (see entire document including column 6, lines 24-41). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the pharmacologically active substance from camphor or lidocaine, as disclosed by Cilento, motivated by the expectation of successfully practicing the invention of Merkle.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 37-52, 55-65, 69-82 and 85-95 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of USPN 6,555,730 to Albrod et al. (hereinafter referred to as Albrod) in view of USPN 5,527,536 to Merkle.

Regarding claims 37-52, 55-65, 69-82 and 85-95, Albrod claims a backing material for medical purposes that is similar to the current application. Albrod does not claim a pharmacologically active substance present in the adhesive, but Merkle discloses that it is known in the medical patch art to include a pharmacologically active substance in an adhesive (see entire document including column 3, lines 4-10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a pharmacologically active substance in the adhesive, as taught by Merkle, in order to provide the tape with an enhanced medical function.

Regarding claims 38 and 70, see claim 3 of Albrod.

Regarding claims 39-41 and 71, see claim 1 of Albrod.

Regarding claims 42 and 73, see claim 10 of Albrod.

Regarding claim 43, see claim 7 of Albrod.

Regarding claims 44 and 74, see claim 11 of Albrod.

Regarding claims 45-46 and 75-76, see claim 1 of Albrod.

Regarding claims 47-48 and 77-78, see claim 20 of Albrod.

Regarding claims 49-52 and 79-82, see claim 16 of Albrod.

Regarding claims 55 and 85, see claim 17 of Albrod.

Regarding claims 56-57 and 86-87, Albrod does not claim specific softening temperatures, but Merkel discloses that the adhesive composition may have a softening point of from 80 to 140C (column 4, lines 55-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the softening temperature from 80 to 140C motivated by the expectation of successfully practicing the invention of Albrod.

Regarding claims 58-59 and 88-89, see claim 13 of Albrod.

Regarding claims 60-61 and 90-91, Merkel discloses that the pharmacologically active substance may be present in therapeutically active amounts (column 3, lines 4-10).

Regarding claims 62 and 92, see claim 21 of Albrod.

Regarding claims 63 and 93, see claim 23 of Albrod.

Regarding claims 64 and 94, see claim 25 of Albrod.

Regarding claims 65 and 95, see claim 9 of Albrod.

Regarding claims 69-82 and 85-95, see claim 2 of Albrod.

Regarding claim 72, see claim 5 of Albrod.

20. Claims 53-54 and 83-84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of USPN 6,555,730 to Albrod in view of USPN 5,527,536 to Merkle as applied to claims 37-52, 55-65, 69-82 and 85-95 above, and further in view of USPN 5,863,977 to Fischer.

Regarding claims 53-54 and 83-84, Merkle does not appear to mention the addition of a diblock copolymer, but Fischer discloses that it is known in the art to add a diblock copolymer to a triblock copolymer adhesive to improve tack properties and/or improve processability (see

entire document including the paragraph bridging columns 2 and 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a diblock copolymer to the triblock copolymer adhesive, as taught by Fischer, to improve tack properties and/or improve processability.

Regarding claims 54 and 84, Merkel discloses that the triblock copolymer may be present in an amount of 10 to 80% and a tackifier may be present in an amount of 20 to 90% (column 4, lines 21-52), therefore, the art teaches that the diblock is to be present in an amount of less than 80% by weight.

21. Claims 66 and 96 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of USPN 6,555,730 to Albrod in view of USPN 5,527,536 to Merkle as applied to claims 37-52, 55-65, 69-82 and 85-95 above, and further in view of USPN 5,489,624 to Kantner.

Merkle does not appear to mention incorporating pharmacologically active agents not in co-mixture with the adhesive, but Kantner discloses that adhesive materials in the medical field can frequently be used to transport drugs through the skin (see entire document including abstract). Kantner discloses several examples of biologically active material that would exist in particle form that can be incorporated into the adhesive (see entire document including column 9, lines 28-41 and column 12, lines 14-19). It would have been obvious to a person having ordinary skill in the art at the time of the invention to incorporate active agents not in co-mixture with the adhesive composition in the medical tape, as disclosed by Kantner, in order to provide various healing properties to the tape.

22. Claims 67 and 97 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of USPN 6,555,730 to Albrod in view of USPN 5,527,536 to Merkle as applied to claims 37-52, 55-65, 69-82 and 85-95 above, and further in view of USPN 5,407,717 to Lucast.

Merkel does not appear to mention sterilizing the adhesive composition, but Lucast '717 discloses that adhesive tapes that are used on human skin must be sterilized (see entire document including column 11, lines 5-10). It would have been obvious to a person having ordinary skill in the art at the time of the invention to sterilize the adhesive composition, as taught by Lucast '717, in order to make it safe for use on human skin.

23. Claims 68 and 98 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of USPN 6,555,730 to Albrod in view of USPN 5,527,536 to Merkle as applied to claims37-52, 55-65, 69-82 and 85-95 above, and further in view of USPN 5,059,189 to Cilento.

Merkle appears to be is silent with regards to specific pharmacologically active substances, therefore, it would have been necessary and thus obvious to look to the prior art for conventional pharmacologically active substances. Cilento provides this conventional teaching showing that it is known in the art to use pharmacologically active substances such as camphor, lidocaine, or the like (see entire document including column 6, lines 24-41). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the pharmacologically active substance from camphor or lidocaine, as disclosed by Cilento, motivated by the expectation of successfully practicing the invention of Merkle.

Response to Arguments

24. Applicant's arguments have been considered but are moot in view of the new grounds of rejection.

Conclusion

25. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew T. Piziali whose telephone number is (571) 272-1541. The examiner can normally be reached on Monday-Friday (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (571) 272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

atp

7/28/06

ANDREW T. PIZIALI
PATENT EXAMINER